REMARKS

Each rejection raised by the Examiner is addressed separately below. In view of the claim amendments noted above and the remarks below, Applicants respectfully request reconsideration of the merits of this patent application.

IN THE CLAIMS

Claims 60, 61, 63, 64, 66 and 67 are pending in this application. No amendments have been made, and no new matter has been added.

CLAIM REJECTIONS - 35 USC § 103

Claims 60, 61, 63, 64, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roche Molecular Biochemicals Catalog, 1999, pages 50-51; Sellman et al. Journal of Bacteriology, Vol 174, No. 13, pages 4350-4355; and Lu et at. BioFeedback, Vol 11, No. 4, pages 464-466, 1991.

The Examiner alleges that the Roche catalog teaches a one step RT-PCR system using a purified DNA polymerase in the substantial absence of manganese. The Examiner goes on to allege that Sellman specifically teach the DNA polymerase enzymes from *Bacillus stearothermophilus (Bst)* require Mg2+ for optimal activity and that Lu teach that subtilisin digestion of the Bst polymerase 1 holoenzyme results in a large fragment that results in the same uniform DNA synthesis as the original full-length enzyme. The Examiner therefore concludes that it would have been obvious to one of skill in the art to practice methods similar to those of the Roche catalog by replacing the *Carboxydotherman hydrogeneformans* polymerase with the Bst polymerase of the present claims. Applicants respectfully disagree.

As previously amended, the claims of the current application recite the DNA polymerase from *Bacillus stearothermophilus (Bst)* type strain 5. In contrast, the DNA polymerase described in the Roche catalog is from a different organism, *Carboxydothermus hydrogenoformans*. Nothing in Roche, Sellman or Lu teach or suggest that replacing the *Carboxydothermus hydrogenoformans* with *Bacillus stearothermophilus (Bst)* type strain 5 will be feasible, let alone successful. In contrast, those with knowledge in the art will understand that particular enzymatic activities, properties and reaction conditions vary for each different enzyme and, based on the present knowledge in the art,

the properties of a DNA polymerase from *Carboxydothermus hydrogenoformans* cannot be used to predict the activities, properties, or reaction conditions for using another enzyme from another source for a particular application.

For example, the organization of *Bacillus stearothermophilus (Bst)* type strain 5 provides at least three different DNA polymerase from *Thermus* species, including *Thermus aquaticus* (Taq) DNA polymerase, *Thermus flavus* (Tfl) DNA polymerase, and *Thermus thermophilus* (Tth) DNA polymerase. Of these three *Thermus* enzymes, only the Tth DNA polymerase can be used for reverse transcription and this enzyme requires manganese ions for this use. The finding by the Applicant that the *Bacillus stearothermophilus (Bst)* type strain 5 DNA polymerase had reverse transcriptase activity in the presence of magnesium and in the substantial absence of manganese ions was surprising and unexpected, and could not have been predicted based on the activities, properties, or reaction conditions of another enzyme from another source.

Further, most, if not all DNA polymerases, catalyze DNA-template-dependent DNA synthesis in the presence of magnesium ions. However, this does not indicate whether or not a DNA polymerase has RNA-template-dependent DNA synthesis (or reverse transcriptase) activity and, if a DNA polymerase does also have reverse transcriptase activity, the fact that it has DNA-dependent DNA polymerase activity in the presence of only magnesium ions without any manganese ions does not indicate that it will have reverse transcriptase activity in the presence of magnesium ions and the absence of manganese ions. For example, Tth DNA polymerase has DNA-dependent DNA polymerase activity in the presence of magnesium ions, but requires manganese ions for reverse transcription. Therefore, the Sellman and Lu references are not relevant to the claims of the present invention.

In view of the above arguments, Applicants request the Examiner to kindly withdraw the objections and allow the claims.

SUMMARY

Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

A one-month extension of time is due in connection with this response. However, if any additional extension of time is required in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the petition fee to Deposit Account No. 17-0055. No other fee is believed to be due in connection with this response. However, if any fee is due in this or any subsequent response, please charge the fee to the same Deposit Account No. 17-0055.

Respectfully submitted,

Date: December 2, 2008

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